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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,823	10/15/2001	James J. Rudnick	S63.2N-14438-US04	4655

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EXAMINER

SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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10/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/977,823	Applicant(s) RUDNICK ET AL.	
	Examiner ANN SCHILLINGER	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 and 21-48 is/are pending in the application.
- 4a) Of the above claim(s) 25, 36, 37 and 43-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 21-24, 26-35, and 38-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 21-24, 26-35, and 38-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant's disclosure does not describe the stent's windings being in direct contact with each other when the stent is in its unexpanded configuration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

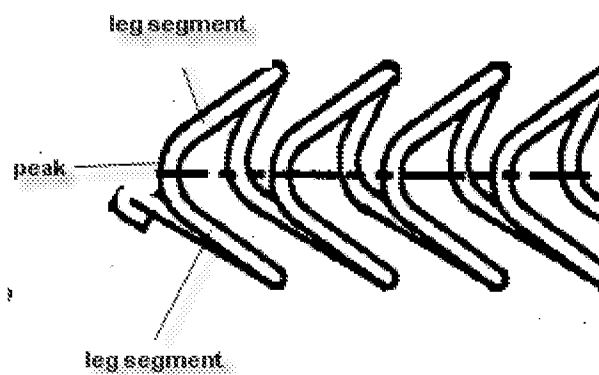
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26, 27, 31-35, and 38-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Timmermans (US Pat. No. 5,183,085). Timmermans discloses the following of claim 26: an intraluminal stem comprising: an unexpanded configuration (col. 3, lines 35-47); and an elongate tubular wire-formed body (10), the wire forming said body being configured into a plurality of waves, each wave of said plurality having a wave peak and a pair of leg segments

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extending from said peak (please see figure below), said waves being arranged in spaced non-overlapping longitudinal succession such that the peak of one said waves is nested within the next adjacent longitudinally successive wave (Figs. 3-4), at least portions of at least two longitudinally successive waves being in direct contact with one another when the stent is in the unexpanded configuration (col. 3, lines 32-47).



Timmermans discloses the following of claim 27: an intraluminal stent of claim 26 wherein said leg segments of each pair are of generally equal length (please see figure above).

Timmermans discloses the following of claim 31: an intraluminal stent of claim 26 wherein said tubular body includes plural wire windings formed into a pattern defining said waves (Figs. 3-4).

Timmermans discloses the following of claim 32: an intraluminal stent of claim 26 wherein said windings are uniformly spaced apart (Figs. 3-4).

Timmermans discloses the following of claim 33: an intraluminal stent of claim 26 wherein said wire windings are formed by a single continuous, helically wound wire (col. 1, lines 54-61).

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Timmermans discloses the following of claim 34: an intraluminal stent comprising: an unexpanded configuration (col. 3, lines 35-47); an elongate wire-formed tubular body (10), said wire-formed body defining a plurality of longitudinally adjacent spaced waves, said longitudinally adjacent spaced waves being non-overlappingly nested (Figs. 3-4), at least two longitudinally successive waves being in direct contact with one another when the stent is in the unexpanded configuration (col. 3, lines 32-47).

Timmermans discloses the following of claim 35: an intraluminal stent of claim 34 wherein said amplitude of said waves is generally uniform (Figs. 3-4).

Timmermans discloses the following of claim 38: an intraluminal stem comprising: an unexpanded configuration (col. 3, lines 35-47); an elongate tubular body (10) being formed of wire (col. 1, lines 54-61) having a pattern defining a plurality of spaced apart successively formed waves along the length thereof, said successively formed waves being non-overlappingly longitudinally nested (Figs. 3-4), at least two longitudinally successive waves being in direct contact with one another when the stent is in the unexpanded configuration (col. 3, lines 32-47).

Timmermans discloses the following of claim 39: an intraluminal stem of claim 38 wherein said pattern is sinusoidal (Figs. 3-4).

Timmermans discloses the following of claim 40: an intraluminal stem of claim 39 wherein said pattern is triangular (Figs. 3-4).

Timmermans discloses the following of claim 41: an intraluminal stem of claim 38 wherein said pattern defines a plurality of continually repeating waves (Figs. 3-4).

Timmermans discloses the following of claim 42: an intraluminal stem of claim 41 wherein said continually repeating waves are uniform (Figs. 3-4).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19, 21, 23, 24, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Timmermans (US Pat. No. 5,183,085) in view of Lau et al. (US Pat. No. 6,165,210).

Timmermans discloses the following of the claimed invention: an elongate tubular stent (10) having an unexpanded configuration; and formed of a helically wound wire (col. 1, lines 54-61) defining non-overlapping, longitudinally nested wire waves (Figs. 3-4). The wire includes a single, continuous, helically wound wire forming uniform first and second windings, at least a portion of the first winding being in direct contact with at least a portion of the second winding when the stent is in the unexpanded configuration (Figs. 3-4; col. 1, lines 54-61; col. 3, lines 32-47). The tubular body of the stent is expandable (col. 2, lines 53-57). Timmermans does not teach that the windings are spaced at a pitch that is less than two times the amplitude of adjacent waves. Lau et al. teaches a self-expandable helical stent that may be formed having a variety of ranges of amplitudes and pitches in col. 11, lines 39-46 and columns 13-14 for the purpose of giving the stent its desired flexibility. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form a stent whose pitch that is less than two times the amplitude of adjacent waves in order to give the stent its desired flexibility.

In addition, it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art, and therefore, one of ordinary skill would have

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developed a stent with a pitch that is less than two times the amplitude of adjacent waves. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Timmermans in view of Lau et al. further in view of Song (US Pat. No. 5,330,500). Timmermans, as modified by Lau et al., teaches the invention substantially as claimed, however, they do not teach a cover on the stent. Song teaches a stent with a mesh cover that may be coated with silicone rubber in col. 3, line 40-62 for the purpose of preventing cell penetration into the prosthesis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Timmermans and Lau et al. by placing a cover on the stent as taught by Song in order to prevent cell penetration.

Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Timmermans in view of Wiktor (US Pat. No. 5,653,727). Timmermans discloses the invention substantially as claimed, however, Timmermans does not disclose the leg segments of the waves being of unequal length. Wiktor teaches a stent with unequal leg segments in Figure 8; col. 5, lines 25-30; and col. 7, lines 16-28 for the purpose of preventing the stent from overstretching. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Timmermans by making the leg segments with an unequal length as taught by Wiktor in order to prevent overstretching.

Response to Arguments

Applicant's arguments filed 8/10/2010 have been fully considered but they are not persuasive. The Applicant contends that Timmermans does not disclose "portions of at least two longitudinally successive waves being in direct contact with one another when the stent is in the

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unexpanded configuration," and "portions of at least two longitudinally adjacent spaced waves being in direct contact with one another when the stent is in the unexpanded configuration." The examiner respectfully disagrees. The Timmermans reference does not explicitly state that the windings of the stent will contact each other when in its unexpanded configuration. However, the stent is made of nitinol which allows for flexibility, and is capable of being compressed into various configurations which may include the windings being in contact with each other without overlapping (col. 3, lines 32-47).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./

Examiner, Art Unit 3774

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774